

## BIOBRICKS FOUNDATION — LEGAL STANDARDS WORKSHOP

### *Assessing Stakeholder Concerns and Developing a Legal Framework*

Samuelson Law, Technology & Public Policy Clinic. UC Berkeley Law School

#### OVERVIEW OF IDENTIFIED ISSUES, CONCERNS, AND IMPLICATIONS FOR THE BBF

Issue	Interviewee concerns	Potential implications for the community	Questions to address
Incentives and Barriers to Participation	<ul style="list-style-type: none"><li>• Consistency with academics' sharing incentives (convenience, efficiency, reputation, community standards, fulfillment of obligations (NIH))</li><li>• Consistency with private sharing incentives (adoption of parts and other strategic motives)</li><li>• Distrust of a complicated framework</li><li>• Uncertainty of data ownership</li><li>• Distaste for a framework with negative rules and limitations</li><li>• Virality and its negative impact on commercialization</li></ul>	<ul style="list-style-type: none"><li>• Create incentives to participate (access to technical tools, journal, accession numbers, online social network, reputation system)</li><li>• Make obligations simple and clear</li><li>• Do not have IP assigned to one player</li><li>• Weigh implications of virality with care</li><li>• Focus on incentives over prohibitions</li></ul>	<ul style="list-style-type: none"><li>• Why do researchers want to share?</li><li>• Why do companies want to share?</li><li>• Is a carrot model (rewards-based) or a stick model (punishment-based) more appropriate?</li></ul>
Ownership, Rights, and Obligations	<ul style="list-style-type: none"><li>• Definition of key terms</li><li>• Authority of researchers to sign license</li><li>• Mechanism of accepting license terms</li><li>• Liability for giving away others' rights</li><li>• Developers giving up too many future interests</li><li>• Unknown third-party rights to, and nebulous ownership of, the repository contents</li><li>• General distrust of a single large organization with many roles</li><li>• Timing and content of disclosure</li></ul>	<ul style="list-style-type: none"><li>• Define legal framework terms very carefully</li><li>• Do not have IP assigned to one player</li><li>• Perform rights clearance for incoming parts</li><li>• Clearly indicate IP rights and limitations for each part (ie flagging)</li><li>• Attempt to limit liability of BBF and repository users and contributors</li><li>• Establish a process to deal with parties in contention over ownership</li></ul>	<ul style="list-style-type: none"><li>• Who owns the repository data?</li><li>• Can researchers assign rights?</li><li>• What rights do contributors give up?</li><li>• What obligations do users take on?</li><li>• What is the <i>quid pro quo</i> of the BioBrick legal framework?</li><li>• How will BBF deal with third party rights?</li></ul>
Enforcement	<ul style="list-style-type: none"><li>• Enforcement could require a lot of work</li><li>• Participants may not give back without enforcement</li><li>• Evolving technical standards could encumber enforcement</li><li>• Enforcement complicated by reverse engineering</li></ul>	<ul style="list-style-type: none"><li>• Establish who will enforce obligations and how</li><li>• Be careful basing obligations on technical standards</li><li>• To promote "give back," use both legal mechanisms and social incentives</li></ul>	<ul style="list-style-type: none"><li>• Who will enforce the rights and obligations of the legal framework?</li><li>• How will enforcement be accomplished? What are the costs and penalties?</li></ul>

Patents	<ul style="list-style-type: none"> <li>• Patents could stifle growth</li> <li>• Burdensome - cost (prosecution &amp; enforcement), jurisdiction, licensing</li> <li>• Public domain as alternative to patenting</li> <li>• Patenting some, but not all, BioBricks might be beneficial</li> <li>• Participation of VCs, industry and some academics is unlikely in a framework imposing patent limitations</li> <li>• A recognized mechanism for international protection</li> <li>• Patents help clarify ownership of repository parts</li> <li>• Public domain is not a guaranteed "patent spoiler"</li> </ul>	<ul style="list-style-type: none"> <li>• Don't allow patented parts</li> <li>• Act as a "patent spoiler" by openly discussing potential parts</li> <li>• Consider a multi-pronged IP approach: patent, trade secret, contract, copyright, etc.</li> <li>• Discourage but allow patents under limited conditions (use patents, system patents, product patents)</li> <li>• BBF patents some parts, forbids patenting of others (prevent "nuisance-level patents")</li> <li>• "Flag" patented Bricks in repository and include some licensing information</li> <li>• Use pro-sharing sentiment of field to advocate for (and demand) liberal licenses for non-commercial use</li> </ul>	<ul style="list-style-type: none"> <li>• Is it possible to satisfy both researchers and industry?</li> <li>• Can BBF afford to not include industry?</li> <li>• How big of a problem is free-riding (industry use of parts without contribution of new parts?)</li> <li>• Are patents a necessary element of a successful BioBrick legal framework?</li> <li>• If so, what should be patentable?</li> </ul>
Repository Quality and Content	<ul style="list-style-type: none"> <li>• Quality and quantity of parts and metadata</li> <li>• Impact of loss of private sector investment</li> <li>• Absence of metadata standards and tools</li> <li>• Commercial sector key to increasing quality</li> </ul>	<ul style="list-style-type: none"> <li>• Provide incentives and tools to submit metadata (e.g. biosafety information, part tracking, improved searchability, impact scores)</li> <li>• Establish technical standards for parts</li> <li>• Integrate both commercial and academic players</li> </ul>	<ul style="list-style-type: none"> <li>• How do we ensure quality and reliability of parts and metadata?</li> <li>• What mechanisms should we use?</li> </ul>

Issue	Suggestions	Questions to address
Perspectives on Roles of the BBF	<ul style="list-style-type: none"> <li>• Set sharing standards for the field</li> <li>• Be a "patent spoiler"</li> <li>• Act as a clearinghouse for licenses to use parts</li> <li>• Be an advocate for a <i>sui generis</i> legal framework</li> <li>• Set up a patent pool and/or become holder of large portfolio of fundamental bricks</li> <li>• Be a coordinator of inexpensive or <i>pro bono</i> patent prosecution</li> </ul>	What roles can and should the BBF play to promote open sharing in the field of synthetic biology?